

(2) Color additive mixtures made with turmeric may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Turmeric may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.615 Turmeric oleoresin.

(a) *Identity.* (1) The color additive turmeric oleoresin is the combination of flavor and color principles obtained from turmeric (*Curcuma longa* L.) by extraction using any one or a combination of the following solvents:

Acetone	Isopropyl alcohol
Ethyl alcohol	Methyl alcohol
Ethylene dichloride	Methylene chloride
Hexane	Trichloroethylene

The definition of turmeric oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric oleoresin under section 401 of the act.

(2) Color additive mixtures made with turmeric oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Turmeric oleoresin shall contain no more residue of the solvents listed under paragraph (a)(1) of this section than is permitted for

the corresponding solvents in spice oleoresins under applicable food additive regulation in parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Turmeric oleoresin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

Subpart B—Drugs

§ 73.1001 Diluents in color additive mixtures for drug use exempt from certification.

The following diluents may be safely used in color additive mixtures that are exempt from certification and which are to be used for coloring drugs, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. Such listing of diluents is not to be construed as superseding any of the other requirements of the Federal Food, Drug, and Cosmetic Act with respect to drugs, including new drugs. If a definition and specification for a particular diluent is not set forth in this subpart, the material shall be of a purity consistent with its intended use.

(a) *Ingested drugs—(1) General use.* Diluents listed in § 73.1(a) and the following:

Substances	Definitions and specifications	Restrictions
Alcohol, specially denatured	As set forth in 26 CFR, pt. 212	As set forth in 26 CFR, pt. 211.

Substances	Definitions and specifications	Restrictions
Cetyl alcohol	As set forth in N.F. XI.	In color coatings for pharmaceutical forms, no residue.
Isopropyl alcohol	
Polyoxyethylene (20) sorbitan monostearate (Polysorbate 60).	As set forth in sec. 172.836 of this chapter.	
Polyoxyethylene (20) sorbitan tristearate (Poly-sorbate 65).	As set forth in sec. 172.838 of this chapter.	
Polysorbate 80	As set forth in sec. 172.840 of this chapter.	
Polyvinyl-pyrrolidone	As set forth in sec. 173.55 of this chapter.	
Sorbitan monooleate.	As set forth in sec. 172.842 of this chapter.	
Sorbitan monostearate		
Sorbitan triolease.		

(2) *Special use; inks for branding pharmaceutical forms.* Items listed in paragraph (a)(1) of this section, § 73.1(b)(1)(i), and the following:

Ethyl lactate
Polyoxyethylene sorbitan monolaurate (20)

(b) *Externally applied drugs.* Diluents listed in paragraph (a)(1) of this section and the following:

Substances	Definitions and specifications
Benzyl alcohol	As set forth in N.F. XI.
Ethyl cellulose	As set forth in § 172.868 of this chapter.
Hydroxyethyl cellulose.	As set forth in § 172.870 of this chapter.
Hydroxypropyl cellulose	

§ 73.1010 Alumina (dried aluminum hydroxide).

(a) *Identity.* (1) The color additive alumina (dried aluminum hydroxide) is a white, odorless, tasteless, amorphous powder consisting essentially of aluminum hydroxide ($\text{Al}_2\text{O}_3 \cdot \text{XH}_2\text{O}$).

(2) Color additive mixtures for drug use made with alumina (dried aluminum hydroxide) may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Alumina (dried aluminum hydroxide) shall conform to the following specifications:

Acidity or alkalinity: Agitate 1 gram of the color additive with 25 milliliters of water and filter. The filtrate shall be neutral to litmus paper.

Matter insoluble in dilute hydrochloric acid, not more than 0.5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Mercury (as Hg), not more than 1 part per million.

Aluminum oxide (Al_2O_3), not less than 50 percent.

(c) *Uses and restrictions.* Alumina (dried aluminum hydroxide) may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.1015 Chromium-cobalt-aluminum oxide.

(a) *Identity.* The color additive chromium-cobalt-aluminum oxide is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide. It may contain small amounts (less than 1 percent each) of oxides of barium, boron, silicon, and nickel.

(b) *Specifications.* Chromium-cobalt-aluminum oxide shall conform to the following specifications:

Chromium, calculated as Cr_2O_3 , 34–37 percent.

Cobalt, calculated as CoO , 29–34 percent.

Aluminum, calculated as Al_2O_3 , 29–35 percent.

Lead (as Pb), not more than 30 parts per million.

Arsenic (as As), not more than 3 parts per million.